federal register

FRIDAY, JUNE 9, 1978
PART IV

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

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Food Labeling

Public Hearings

[4110-03]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[Docket No. 78N-0158]

FOOD LABELING

Hearings

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), and the Federal Trade Commission (FTC) announce a series of five public hearings to discuss several issues related to food labeling, including ingredient labeling, nutrition labeling, and imitation foods.

DATES AND LOCATIONS: August 22-23, 1978—Century II Theater, 225 West Douglas, Wichita, Kans. September 18-19, 1978—Little Rock Convention Center, Robinson Auditorium, Room 102 or 103, Markham and Broadway, Little Rock, Ark. September 27-28, 1978—HEW Auditorium, 330 Independence Avenue, SW., Washington, D.C. October 12-13, 1978—Fremont Building, 215 Fremont Street, EPA Conference Room, 6th floor, San Francisco, Calif. October 25-26, 1978—Howard Johnson's 57 Motel, 200 Stuart Street, Boston, Mass.

FOR FURTHER INFORMATION CONTACT:

Taylor Quinn, Bureau of Foods (HFF-300), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C Street SW., Washington, D.C. 20240, 202-245-1243.

SUPPLEMENTARY INFORMATION: The Commissioner of Food and Drugs announced in October 1977 his intention to hold hearings on the broad subjects of ingredient labeling, nutrition labeling, food fortification, and related matters. As explained in his announcement, such hearings are essential in order to gather information and opinions on the subject of food labeling. This public input will in turn provide a basis for development of a comprehensive strategy aimed at providing consumers with useful nutrition-oriented information on the labels of all food products.

Representatives from FDA, FTC, and USDA have been meeting regularly since the announcement of the hearings in order to work out the details of the hearings and identify the subjects that need to be discussed. The hearings will be limited to discussions on the following topics:

1. Ingredient labeling.
2. Nutritional labeling and other dietary information.
3. Open date labeling.
4. Imitation and substitute foods.
5. Food fortification.
6. The total food label.
7. Safe and suitable ingredients.

A discussion on each of the above topics is published as an appendix to this notice. Copies of the discussion are also on file in the office of the Hearing Clerk, Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857. Additional copies may be obtained from FDA offices located in most major metropolitan areas and from the contact person identified above.

The hearings will be open to the public and will be held on the dates and at the locations listed above. Each hearing will begin at 9:30 a.m. and will be presided over by either an FDA or USDA representative. All seven topics will be discussed at each hearing.

The hearings will be conducted in accordance with Title 21 of the Code of Federal Regulations, Part 15—Public Hearing Before The Commissioner. Any person who desires to make a presentation at a particular hearing may do so by simply indicating this wish at the time of the hearing. However, for scheduling purposes, we encourage those who can to fill out and return the notice of participation form attached to this notice to Taylor Quinn at the address given for him above.

Individuals or organizations will be allowed only one opportunity to present their views in the course of the five hearings. Consumers with no organizational affiliation will be allowed to present their views first at each hearing. These are public hearings and are open to all interested parties. However, organized consumer groups as well as regulated industries and their associations are experienced in the use of other avenues for making their views known to the agency, including making written submissions in response to FEDERAL REGISTER notices. It is the special aim of these national hearings to provide an avenue for the expression of the views of individuals. In allocating time at the hearings, therefore, we intend to extend preference to such submissions. Those who are unable to appear in person may submit information and views in writing to the Hearing Clerk by close of business November 10, 1978, at the address given above. Written submissions will also be accepted at the time of each hearing for those who want additional information included in the record. Consumers with no organizational affiliation may submit a single copy of their information and views, but others should submit four copies. The submissions should be identified with the docket number found in brackets in the heading of this document. Received submissions may be seen in the office of the Hearing Clerk from 9 a.m. to 4 p.m., Monday through Friday.

Dated: June 2, 1978.

DONALD KENNEDY,
Commissioner of Food and Drugs.

FOOD LABELING HEARINGS
NOTICE OF PARTICIPATION

Please enter participation of: _____
(Name

_____
(Street Address)

_____
(City, State, Zip Code)

I am representing (if other than self): _____

_____

1. I will make an oral presentation at the _____
(Name of City)

Food Labeling Hearings. I request _____ minutes for my presentation.

I will be speaking on the following topics:

and/or

2. I am submitting for the record the attached comments on the following food labeling topics:

TOPICS

[] Ingredient Labeling
[] Nutrition/Dietary Labeling
[] Open Dating
[] Imitation and Substitute Foods
[] Food Fortification
[] Total Food Label
[] Safe and Suitable Ingredients

_____
(Signature)

INTRODUCTION

Federal laws governing the labeling of food are enforced by the United States Department of Agriculture (meat and poultry products) and the Food and Drug Administration (all other food). These Federal laws were originally passed in 1906, and although some revisions have been made since then, the basic concepts with respect to food labeling have remained unchanged for about 40 years. Significant advances in food technology during this time, coupled with increasing demand for extensive and sophisticated information about food products and increasingly antiquated statutes, have led to a complex set of food labeling regulations.

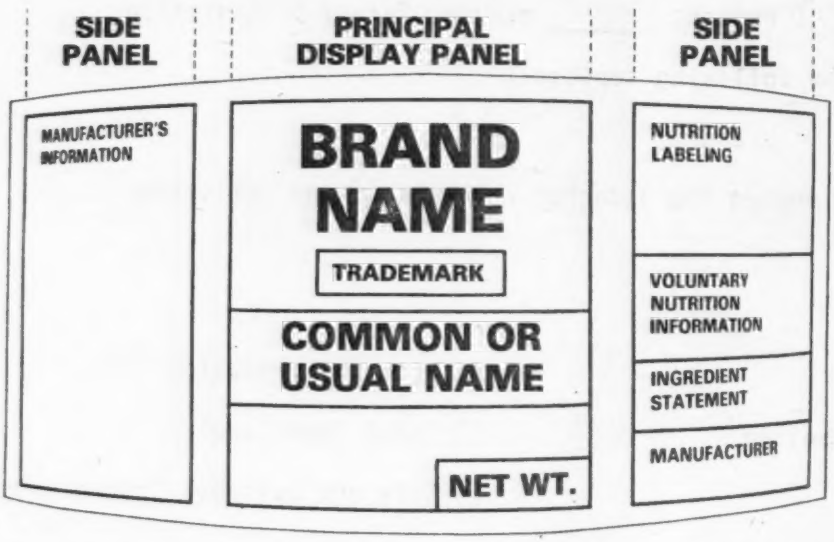
The current goal of the Food and Drug Administration (FDA) and the United States Department of Agriculture (USDA) is the development of an overall labeling strategy that provides consumers with information they want and need. In order to achieve this goal, a number of programs are underway including an audit of existing regulations to determine whether labeling regulations are adequate and to identify candidates for simplification, improved internal consistency, or elimination. The Federal Trade Commission (FTC) is also interested in food labeling because of its responsibility for regulating food advertising.

As part of the comprehensive review of food labeling, FDA, in cooperation with USDA and FTC, is seeking comments from consumers and other interested groups through public hearings. These hearings will elicit public concerns and ideas about:

Ingredient labeling.
Nutrition labeling and other dietary information.
Open date labeling.
Imitation and substitute foods.
Food fortification.
The total food label.
Safe and suitable ingredients.

As an aid in focusing the discussion of these issues, background information and specific questions are provided for each topic. References are also furnished for a few pertinent statutory provisions, regulations, and judicial decisions. To aid in understanding food labeling terminology, examples of food labels are provided. Label No. 1 shows the principal food labeling elements.

LABEL 1



INGREDIENT LABELING

In this section, we discuss how ingredients are listed on labels of both standardized and nonstandardized food. Comments are desired on these related topics:

Listing of ingredients in order of predominance.
Quantitative ingredient listing.
Percentage of ingredient as part of product name.
Names of ingredients.
Changes in ingredients.

LISTING OF INGREDIENTS IN ORDER OF PREDOMINANCE

Government regulations called standards of identity define the composition of many foods, state which optional ingredients may be used, and specify those ingredients which must be declared on the label. Examples of standardized foods are most canned fruits and vegetables, milk, cheeses, ice cream, breads, margarine, and certain seafoods, sweeteners and food dressings. Required or mandatory ingredients used in such standardized foods are exempt by law from label declaration. FDA has sought the legal authority to require the declaration of mandatory ingredients for a number of years. Proposed laws would require listing of ingredients in all foods, whether standardized or not.

Earlier standards required declaration of only a limited number of optional ingredients since the specific ingredients which could be used were named in the standard. Most standards have been or are being revised to permit greater flexibility in the use of ingredients and, at the same time, to require the declaration of all optional ingredients. The law requires, with few exceptions (e.g. spices, flavors, colors), the label declaration of all ingredients in foods which are not standardized. Labels for all meat and poultry products, whether standardized or not, must list ingredients. Government regulations require that whenever ingredients must be declared on the label, the ingredients must be listed in descending order of predominance by weight.

Label No. 2 for canned peas shows the listing of ingredients in order of predominance.

1. Some people may not know that food ingredients are listed on labels in the order of predominance. Should the label state that foods are listed in order of predominance?

2. Should exceptions be permitted from the order of predominance requirement for ingredients present in small amounts, such as spices or food colorings? FDA permits few exceptions, but some think we should be more flexible to permit minor changes in ingredients in order to keep costs down.

QUANTITATIVE INGREDIENT LISTING

Some consumer representatives have proposed requiring that labels for all food declare the percent of ingredients in the ingredient statement. Bills to do this have been introduced into Congress. On September 7, 1976, FDA published a proposal requiring percentage ingredient labeling for infant foods. Use of percentage ingredient listing would provide an ingredient statement such as the following for canned peas:

Ingredients: Peas 65 percent, Water 32 percent, Sugar 2 percent, Salt 1 percent

There are other ways of declaring the amount of ingredients, such as giving the weight of each ingredient per ounce or gram of food.

3. Should labels for all foods declare the amount of ingredients in the product? How would quantitative ingredient labeling be more helpful than the present method of listing ingredients in descending order of predominance? Should the amount of each ingredient

be declared using percentages or some other method?

4. Do you see any value in knowing the amount of ingredients present in small amounts, for example, spices, and flavorings? Do you favor a cutoff level below which ingredients present in small amounts would have to be listed, but not the amount? If so, what should the cut-off level be?

5. Should a cost/benefit study be conducted to help the government arrive at a decision on quantitative ingredient labeling, or should the decision be made on other grounds, such as the consumer's "right to know?" If you think cost should be a consideration, would you be willing to pay for the information? How much?

6. The FDA proposal for infant foods would require percentage ingredient labeling in 5 percent increments. This means that the amount of each ingredient present would be declared by rounding off to the nearest 5 percent. Would this degree of accuracy be satisfactory for all foods? If not, what increments would be better?

Percentage of Ingredients as Part of Product Name

FDA requires a declaration of the percentage of some "characterizing" ingredients as part of the name of some foods when the amount of the ingredients has a material bearing on the consumer's acceptrance of the food. For example, if a shrimp cocktail consists of 50 percent shrimp, the official name of the product is "Shrimp Cocktail—Contains 50 Percent Shrimp."

7. Should a declaration of the percentage of characterizing ingredients as part of the name of food be required for more foods? Which foods? Which ingredients in those foods do you consider to be characterizing? How important a priority is this to you?

Name of Ingredients

Most ingredients must be listed on the label by the specific name of the ingredient. There are some exceptions to this rule. Under the law, spices, flavorings and colors may be declared in the ingredient statement without naming the specific ingredient used. Furthermore, generic or collective names can sometimes be used instead of the specific name. (Example: whey can be declared when it is reconstituted whey. See Label No. 3 for American Cheese Food.) Some consumers are confused by long chemical names, while others want some specific information about ingredient identity because they may be allergic to certain ingredients.

8. Do you favor changing the law to require listing of specific spices, flavors and color ingredients?

9. Are specific names of certain ingredients confusing? What changes do you suggest?

10. Under the law, artificial color may be used in butter, cheese and ice cream without the label declaring the presence of the color. Do you think this exemption should be changed?

11. The regulations allow for some flexibility in the declaration of a fat or oil ingredient. For example, a vegetable oil may be declared as follows: "vegetable oil shortening (contains one or more of the following: soybean oil, palm oil, and/or corn oil)." Food producers indicate that such labeling allows flexibility in purchasing fats or oils according to best available price. Do you believe such labeling should be permitted? Should this method of labeling be extended to other instances where multiple ingredients are similary interchangeable?

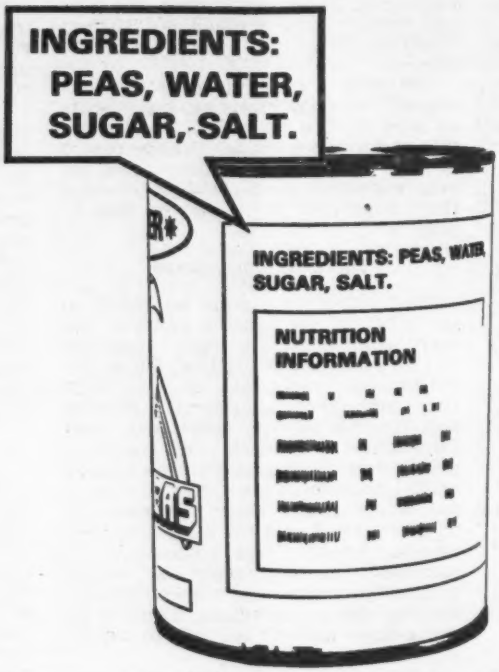
Changes in Ingredients

Some consumers want to require that food labels be flagged in some way when a change is made in the ingredients used. This is because once a product has been used for some time, the consumer might not realize that an ingredient change was made.

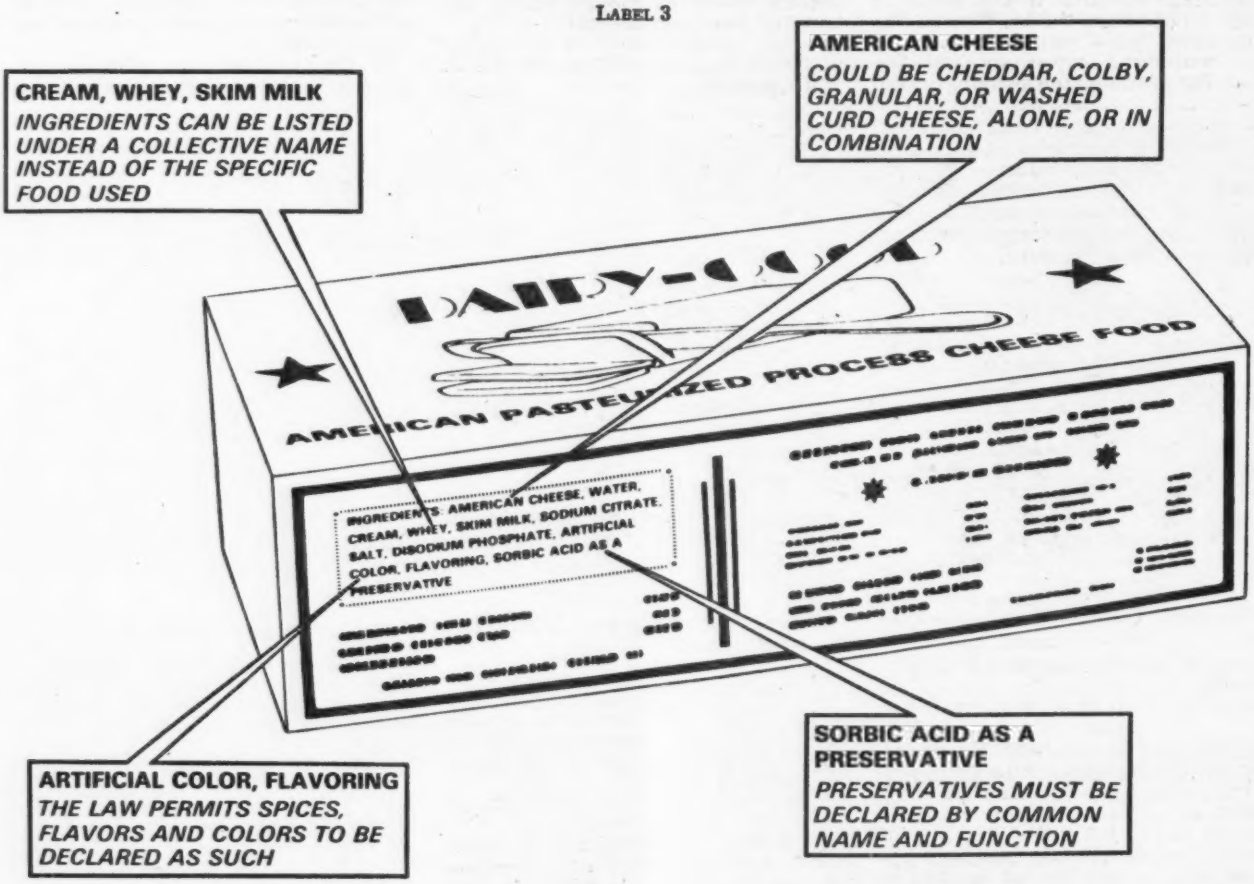
12. Do you believe that a change in ingredients should be prominently noted on the label? What kind of change (any new ingredient, removal of ingredient, etc.) should trigger the special notice?

13. Do you have any other suggestions on ingredient labeling?

LABEL 2



LABEL 3


CREAM, WHEY, SKIM MILK
INGREDIENTS CAN BE LISTED UNDER A COLLECTIVE NAME INSTEAD OF THE SPECIFIC FOOD USED
AMERICAN CHEESE
COULD BE CHEDDAR, COLBY, GRANULAR, OR WASHED CURD CHEESE, ALONE, OR IN COMBINATION
AMERICAN PASTEURIZED PROCESS CHEESE FOOD
INGREDIENTS: AMERICAN CHEESE, WATER, CREAM, WHEY, SKIM MILK, SODIUM CITRATE, SALT, DISODIUM PHOSPHATE, ARTIFICIAL COLOR, FLAVORING, SORBIC ACID AS A PRESERVATIVE
ARTIFICIAL COLOR, FLAVORING
THE LAW PERMITS SPICES, FLAVORS AND COLORS TO BE DECLARED AS SUCH
SORBIC ACID AS A PRESERVATIVE
PRESERVATIVES MUST BE DECLARED BY COMMON NAME AND FUNCTION

NUTRITION LABELING AND OTHER DIETARY INFORMATION

BACKGROUND

Nutrition labeling is quite new. Consumer interest in nutrition labeling came into focus in late 1969 at the White House Conference on Food, Nutrition and Health. Different ways to present nutrition information on the food labels were studied during 1970 and 1971. In 1972, FDA proposed a system for nutrition labeling, and many comments from consumers, scientists, industry, and other government agencies were received. The proposal was modified and issued as a final regulation in 1973. Nutrition labeling began to appear in grocery stores in 1973, and its use has expanded greatly since then. Many billions of dollars worth of our foods are known to be nutrition labeled, but what proportion of our total $120 billion annual food bill is accompanied by such labels is not known. An FDA nationwide survey to find the answer will be finished this summer.

Nutrition labeling is partly a voluntary program. It becomes mandatory only when a processor makes any kind of claim about the food's nutritional value in labeling or advertising, or when the food is enriched with any essential nutrients. The program applies to foods regulated by FDA (most foods, except meat and poultry which are regulated by USDA). USDA has also approved the use of the same type of labeling on many types of processed meat and poultry products. When a food label contains nutrition information, that information must be provided in a standard format: Serving size, servings per container, and then for each serving—the calories and protein, carbohydrates and fats in grams, followed by protein and a minimum of seven specified vitamins and minerals in terms of the percentage of the U.S. Recommended Daily Allowances (U.S. RDA's). Quantitative information on the content of other vitamins and minerals, sodium and potassium, cholesterol, and polyunsaturated and saturated fatty acids may also be included in a standardized way. The standardized way of presenting all this information is thought to be important to avoid confronting the consumer with multiple ways of expressing the same information. Typical examples of nutrition labeling are shown as Labels Nos. 4 (Corn Flakes) and 5 (Salad Dressing).

The basic purpose of nutrition labeling is to provide accurate nutrition information about each food. There are four basic constraints to this:

The law does not provide FDA with express authority to require nutrition labeling on all foods.

Nutrition labeling may be costly because of the expense of analyzing products for nutrient content. FDA does not wish to take steps that would significantly increase food prices unless there is an important public health reason for doing so.

Knowledge of the nutrient content of some foods and the natural variation in this content is poor. This is particularly true of fresh fruits and vegetables, which are specifically exempted from the nutrition labeling regulation for this reason.

Knowledge about nutrition generally is quite limited. For example, we do not yet know all the effects of nutrients on health.

SOME ISSUES

Current nutrition labeling policies and regulations are considered by the government to be a good first step in the right direction, but it is recognized that the current system may not be the best possible. Consumer research studies are underway to try to improve nutrition labeling, but the government also needs help through the public hearing process. The current studies focus on the specific kinds of information needed and wanted as well as the most understandable way to present the information. After five years of experience in the marketplace, the time has come to consider the need for change.

A very important question is whether nutrition labeling is useful. The key to this issue is proper education in how to use nutrition information in selecting well-balanced diets and to minimize consumption of those food components that some consumers may wish to avoid for health or other reasons.

1. Do you think nutrition labeling is useful? If not, do you think it can be made useful through other programs. If so, what programs?

2. On what kinds of food should nutrition labeling be required? Do you think it would be useful to require nutrition labeling on all foods? Would you be willing to pay more for foods that provide this information?

One problem concerns the way information is presented.

Serving sizes are expressed in common household measures (ounces, teaspoons, pieces, etc.).

Calories are expressed as calories in a serving.

Sodium, potassium and cholesterol are in milligrams.

Protein, vitamins and minerals are in percentage of the recommended daily allowances (U.S. RDA's).

Some nutrients (e.g. sugar) are expressed in grams per serving.

This degree of complexity may ultimately prove to be necessary because there may not be a better way, but the subject needs to be explored. For example, a suggestion has been made that all the nutrients be declared as amounts in the metric system (milligrams, etc.) per 100 calories, or that nutrients be declared as percentages of the daily allowance per 100 calories. This suggestion is referred to as the "nutrient density" concept. Another part of the problem is whether or not it would be better to eliminate as many numbers as possible, switching to some form of pictorial representation such as bar graphs or circular wedge charts ("pie charts"). It is also possible to combine nutrient density with pictorial methods. It is important, however, to think about how much education would be required to understand either one or both of these approaches. In addition, a system could conceivably be devised under which nutrition labeling would appear as words describing each food as an excellent, good, fair, poor, or zero source of each nutrient. These descriptive words would, of course, have to be defined in quantitative terms by regulation, but the quantities themselves need not appear on the label.

3. Rather than providing information in metric units and % U.S. RDA's, should some other approach be used, such as nutrient density? Or should a system be devised that would permit simplification of labeling so that foods could be stated to be excellent, good, fair, poor, or zero sources of each nutrient? Do you have suggestions on how this might be done? If such changes were made, what implications would the change have for nutrition education?

4. Should the format be changed to include as much of the information as possible in graphic or pictorial form? Do you have suggestions on how to do this?

5. Do you think it would be possible to develop a "nutrition score" for each food? If so, how would you do it?

6. Do you think the current nutrition label has too much or too little information? If too little, what further information do you think should be included? If too much, what information do you think should be eliminated?

7. Do you have other suggestions on how to present nutrition information to consumers?

Another problem is the actual information itself. The information currently provided consists primarily of energy and nutrients known through nutrition research to be needed by humans. There is concern, however, whether this is sufficient. Some persons have suggested that the label give more information about substances in food that some consumers want to avoid for health or other reasons. Primarily because of tooth decay problems, some feel that carbohydrate information should be increased to show the quantity of sugar (sucrose) and other simple carbohydrates as compared with the quantity of starches

and other comples carbohydrates. (This type of information is now voluntarily provided on the labels of many read-to-eat breakfast cereals, but is not required by FDA.)

There also is interest in more explicit information on salt or sodium content primarily because of high blood pressure problems, and some concern about the need for more information on vitamins and minerals that may be in short supply in some American diets, such as folic acid and zinc. Coupled with these specific types of additional information is the matter of prominence of display. Some feel that the content of certain components should not only be declared on the nutrition label itself, but should be routinely emphasized on the front of the label; for example, the content of calories, percentage of sugars, salt, and cholesterol. Many of these concerns are brought out in the recent publication from the Senate Select Committee on Nutrition and Human Needs entitled "Dietary Goals for the United States" (Second Edition, December 1977, 95th Congress, 1st Session, U.S. Government Printing Office, Washington, DC 20402). This year, FDA will propose that sodium and potassium content be declared on all nutrition labels. The agency also is considering ways to improve cholestrol labeling, and is in the process of developing a policy on sugar labeling.

8. If you were on a special diet, how could food be better labeled to help you to make food purchases wisely?

9. Do your think information on certain constituents should be required on the label; for example, amount of calories, sugars, sodium, fiber and/or cholesterol? Are there other examples? Should this type of information be provided on the nutrition label, on the principal display panel, or in both places?

10. Some consumers have suggested that the percentage of sugar in certain foods be declared as part of their names because they believe the amount of sugar is important to consumers for various reasons. Do you think that more information should appear on the label about the percentage or amount of sugar in food? For which foods should this information be provided? Should the amount of all sugars in the food be declared, including sugars added as a separate ingredient and those present in other ingredients? How should this information be presented on the label?

A related issue is how far we should go in determining when dietary information may be included in labeling claims or in the names of food. FDA is developing a definition for "low cholesterol" and "cholesterol reduced foods."

11. A similar problem exists concerning the sodium or salt content of foods.

Should the government continue to develop systems for determining when labeling can make claims describing food as "cholesterol free", "low sodium", etc. Or is it better simply to provide consumers with quantitative information without further attempts to describe the nature of the food?

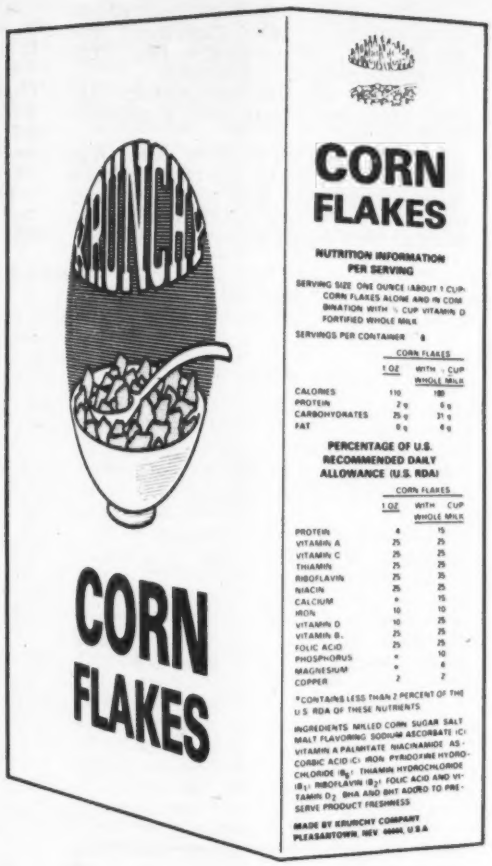
FDA has generally objected to claims in food labeling that a nutrient or other ingredient will cure or prevent a disease. These claims may make the food a drug, subject to the requirements governing drugs, including the requirements that the product be effective for the claimed purpose.

Furthermore, no disease-related or other claim can be made in food labeling if the claim is misleading. FDA has believed that it is difficult to phrase disease-related claims without being misleading because the subject may be scientifically controversial and because it is the total daily diet, not individual food items, that determines nutritional health or reduces risk of diet-related diseases. FDA has, for example, taken the position that it would be misleading to suggest that use of a specific low cholesterol food will prevent heart disease.

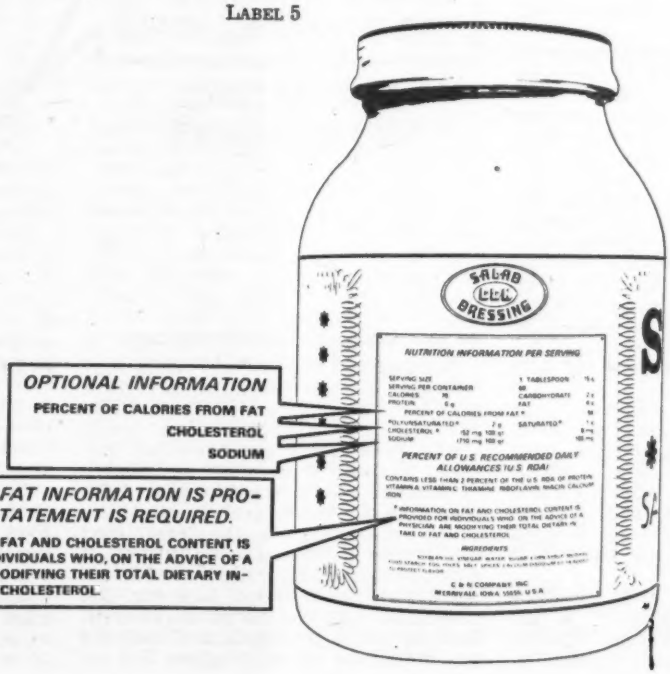
12. Should labels be permitted to contain statements about the relationship between use of the food and the prevention of diseases? If so, what type of evidence should be required in support of such statements? Does such disease information belong more properly in the classroom and doctor's office?

13. Are there other types of dietary information that should be included in food labeling?

LABEL 4


CRUNCHY
CORN
FLAKES
CORN FLAKES
NUTRITION INFORMATION PER SERVING
SERVING SIZE ONE OUNCE (ABOUT 1 CUP) CORN FLAKES ALONE AND IN COMBINATION WITH ½ CUP VITAMIN D FORTIFIED WHOLE MILK
SERVINGS PER CONTAINER 6
CORN FLAKES
1 OZ
WITH ½ CUP WHOLE MILK
CALORIES 110 160
PROTEIN 2 g 6 g
CARBOHYDRATES 25 g 31 g
FAT 0 g 4 g
PERCENTAGE OF U.S. RECOMMENDED DAILY ALLOWANCE (U.S. RDA)
CORN FLAKES
1 OZ
WITH ½ CUP WHOLE MILK
PROTEIN 4 15
VITAMIN A 25 25
VITAMIN C 25 25
THIAMIN 25 25
RIBOFLAVIN 25 25
NIACIN 25 25
CALCIUM * 15
IRON 10 10
VITAMIN D 10 25
VITAMIN B6 25 25
FOLIC ACID 25 25
PHOSPHORUS * 10
MAGNESIUM * 4
COPPER 2 2
*CONTAINS LESS THAN 2 PERCENT OF THE U.S. RDA OF THESE NUTRIENTS
INGREDIENTS MILLED CORN, SUGAR, SALT, MALT FLAVORING, SODIUM ASCORBATE (C), VITAMIN A PALMITATE, NIACINAMIDE, ASCORBIC ACID (C), IRON, PYRIDOXINE HYDROCHLORIDE (B_6), THIAMIN HYDROCHLORIDE (B_1), RIBOFLAVIN (B_2), FOLIC ACID AND VITAMIN D_2. BHA AND BHT ADDED TO PRESERVE PRODUCT FRESHNESS
MADE BY KRUNCHY COMPANY
PLEASANTOWN, NEV. 00000, U.S.A.

LABEL 5


SALAD DRESSING
NUTRITION INFORMATION PER SERVING
SERVING SIZE 1 TABLESPOON
SERVING PER CONTAINER 60
CALORIES 70 CARBOHYDRATE 2 g
PROTEIN 0 g FAT 8 g
PERCENT OF CALORIES FROM FAT *
POLYUNSATURATED* 2 g SATURATED* 1 g
CHOLESTEROL * 52 mg 100 g 9 mg
SODIUM 170 mg 100 g 100 mg
PERCENT OF U.S. RECOMMENDED DAILY ALLOWANCES (U.S. RDA)
CONTAINS LESS THAN 2 PERCENT OF THE U.S. RDA OF PROTEIN, VITAMIN A, VITAMIN C, THIAMINE, RIBOFLAVIN, NIACIN, CALCIUM, IRON
* INFORMATION ON FAT AND CHOLESTEROL CONTENT IS PROVIDED FOR INDIVIDUALS WHO, ON THE ADVICE OF A PHYSICIAN, ARE MODIFYING THEIR TOTAL DIETARY INTAKE OF FAT AND CHOLESTEROL
INGREDIENTS
C & R COMPANY, INC.
MERRIVALE, IOWA 55555, U.S.A.

OPTIONAL INFORMATION

PERCENT OF CALORIES FROM FAT

CHOLESTEROL

SODIUM

IF OPTIONAL FAT INFORMATION IS PROVIDED, THIS STATEMENT IS REQUIRED.

INFORMATION ON FAT AND CHOLESTEROL CONTENT IS PROVIDED FOR INDIVIDUALS WHO, ON THE ADVICE OF A PHYSICIAN, ARE MODIFYING THEIR TOTAL DIETARY INTAKE OF FAT AND CHOLESTEROL.

Open Date Labeling

An open date represents a calendar date on a food package indicating product freshness. It tells either when a product was packaged or processed, when the product should be sold by the store, or when the product should be used by the consumer. Open dating is voluntary under federal law, but mandatory for perishable foods in a few local jurisdictions. Some manufacturers voluntarily provide open date labeling.

With limited exception, the open date does not have to be accompanied by prefixes such as "Sell By," "Use By," or "Better If Used By" that tell the consumer its meaning. The exception relates to meat and poultry food products covered by the Federal Meat and Poultry Inspection Acts, which represent 25 to 30 percent of the food sold in grocery stores. Under regulations administered by USDA's Food Safety and Quality Service, if a calendar date is shown on the label of a meat or poultry food product, it must be explained in terms of "packing" date, "Sell By" date, or "Use Before" date.

Alternatively, USDA allows processors to label meat and poultry products with statements such as "Full freshness 10 days beyond date shown, when stored at 40° F or below." However, such labeling must be supported by test data that show that the statement is true. USDA also requires frozen or refrigerated meat and poultry products to be labeled "Keep Frozen" or "Keep Refrigerated."

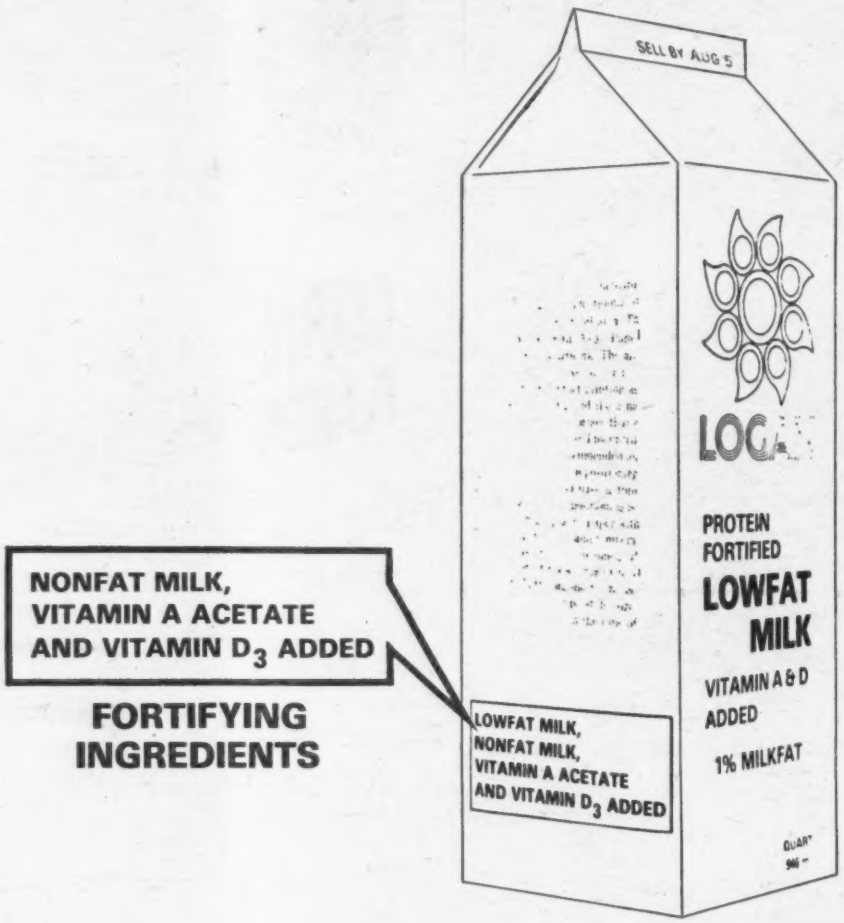
Four types of open dates are in common use:

1. Pack date—the date of final packing.
2. Pull date—the last recommended day of retail sale that allows for sufficient home storage and use time.
3. Quality assurance date—the date after which the product is not likely to be at peak quality, e.g., "Sell By (date)."
4. Expiration date—the last day the product should be used for assured quality, e.g., "Do not use after (date)."

An example of open date labeling appears on Label No. 6, Low Fat Milk.

1. Should open dating be required for all foods, only perishable foods, or only selected perishable foods?
2. Should an explanation of the date shown be required?
3. Which of the four common types of open date labeling is most meaningful? Should different products have different types of open date labeling, such as pull dates for perishables and pack dates for canned food? Should certain products have two dates, such as the pull date and the expiration date?
4. Should storage and handling instructions be mandatory? Would home storage and handling instructions make open dating more useful?
5. Should all open dates be uniform with respect to label placement and application techniques, i.e., ink marked or pressure embossed?
6. Is an alpha-numeric (April 18) date more acceptable then a numeric (4-18) date?
7. Is open dating of more value than other information on the label? Which information? Are you willing to pay more for products that have open dating? How much more per week?
8. How often are foods thrown out because the open date on the package is considered to be a throwout date?
9. Would a labeling sticker that changed color, say from white to red, when temperature or time had affected the product be a more meaningful way of informing about the freshness of a food product?
10. Do you favor allowing retailers to sell "out of date products" (such as day old bread)?

Label 6



Imitation and Substitute Foods

Substitute foods are any foods that resemble and are intended to replace another food. Some substitute foods are considered to be "imitation" foods. Under Federal law, any food that imitates another food must be labeled "imitation ——." Traditionally, FDA accepted the concept that substitute foods were inferior to the "real" food and has to be labeled as imitations. If a standard of identity were established for the substitute food, however, the substitute was viewed as a different food from the real food, and thus did not have to be called imitation. For example, salad dressing does not have to be called "Imitation Mayonnaise."

In 1973, FDA reviewed its policy and decided to identify nutritionally inferior foods by requiring them to be called "imitation," but to allow all other substitute foods to be sold without being called imitation, if they bore a name that accurately described the food. FDA made this change because it believed that the meaning of imitation was confusing.

Although the name "imitation" implies that the substitute food is inferior, some substitute foods may be equal to or better than the real food in nu-

trition. The substitute food might, for example, have lower amounts of fat and calories, which are rarely viewed today as valuable attributes. FDA also believed that its new policy would encourage manufacturers to make substitute foods nutritionally equivalent to the foods they replace, in order to avoid having to use the "imitation" label. FDA's interpretation of imitation has been upheld by the courts.

1. What kind of food should be called "imitation"?

2. What does the word "imitation" on the food label mean to you?

3. Should a substitute food always be called an "imitation" food, to indicate what it is not, in addition to being labeled with a name that identifies what it is; for example, should margarine be named "imitation butter" in addition to being labeled "margarine"? Why?

4. If a food purports to be a standardized food but does not conform to a standard of identity, should it be possible to sell the food, and, if so, under what name? Should the name of the food simply describe the difference from the standardized food? Should the food be called an "imitation"?

5. What information should be included in the name or on the label of substitute foods to inform consumers about the food? For example, should the name state the percentage of characterizing (important) ingredients?

In deciding whether a substitute food is nutritionally inferior and must be called "imitation", FDA looks at the nutrients for which there are U.S. Recommended Daily Allowances (RDA) and which are present in conventional foods at 2 percent or more of the U.S. RDA per serving of each nutrient. If there were sufficient scientific support, FDA could include other nutritional characteristics, such as the nature of the carbohydrate or fat, in the criteria for nutritional equivalence.

6. What criteria should be used to judge whether a food is nutritionally inferior? Should nutritional inferiority include the type of fat or carbohydrate (sugar, starch, fiber)? Should nutritional inferiority include trace minerals or other nutrients in addition to those for which RDA's have been established?

7. Should substitute foods that are nutritionally inferior be labeled to indicate that the food is nutritionally inferior? Do you think the term "imitation" is adequate to indicate that a substitute food is nutritionally inferior? What more information should be required?

8. Should prior approval by the government be required before a manufacturer can sell nutritionally equivalent substitute food under an accurate and descriptive name without "imitation" labeling? Why?

9. As discussed earlier, substitute foods that are nutritionally inferior must be labeled "imitation." Is the word "imitation" enough, or should the manufacturers be required to make substitute foods nutritionally equivalent? Should substitute foods have characteristics other than simply being identical in nutrient content? If so, what are the other characteristics?

Should even nutritionally equivalent substitute foods be labeled "imitation."

11. Do you have other suggestions about how substitute foods and imitation foods should be named and labeled?

Food Fortification

Food fortification refers to the addition of nutrients to foods. Examples are the addition of vitamin D to milk, iodine to table salt, and various vitamins and minerals to ready-to-eat breakfast cereals.

FDA does not have a general, overall regulation that requires or prohibits food fortification. FDA has established some standards of identity that prescribe the extent to which some standardized food must be fortified. Examples are enriched bread, which must contain levels of three vitamins and one mineral, and margarine, which must contain a specific amount of vitamin A. The standard for soda water, on the other hand, specifically prohibits the addition of nutrients on the grounds that they are unsuitable optional ingredients. FDA's policies on imitation labeling encourage the fortification of a food substitute to make it nutritionally equivalent to the food substituted for.

Those who favor food fortification believe that fortification is appropriate to counteract dietary insufficiencies and prevent the occurrence of dietary deficiencies, to restore nutrients unavoidably lost in the processing of foods, and to enhance the balance of nutrients to calories in foods. For many years, nutrients added to common foods have contributed substantial proportions of the total amount of many essential vitamins and minerals in our national food supply. The addition of niacin to bread (and other baked cereal-based staples and rice) in the enrichment program in the 1940's was responsible for the decline and virtual disapearance of pellagra, which was then endemic in the South. The nutrient fortification of milk for infant feeding is an example of the addition of nutrients to prevent the occurrence of a dietary deficiency in a very susceptible population.

Because no regulations or official policy guidelines exist, over-fortification as well as inapproprite fortification of foods may occur. Over fortification in both quantity and kind of nutrients can lead to unusual and excessive intakes of some nutrients, particularly if it encourages consumption of a food which, itself, may be considered to be nutritionally undesirable by being high in calories or containing large amounts of salt or simply being a "fun food." Indiscriminate fortification might also imply to some consumers that fortification of any kind makes a good food out of one with less desirable nutritional characteristics. As an example, some believe that adding vitamins and minerals to potato chips is inappropriate fortification.

The nature of our food supply is changing. We eat an even higher proportion of almost-ready-to-eat foods and meals than a generation ago; some foods are highly processed conventional foods and others are formulated from a wide variety of ingredients. This change is coming about primarily because of economic factors and new living styles. More consumers have the ability to buy according to their preferences, and the economics of agricultural production and the national food marketing system foster the change. More plant-derived than animal-derived foods may be eaten in the future. Some believe that limited fortification of these kinds of foods would be a desirable form of health maintenance or protection.

Please provide comments on when food fortification is appropriate and the extent to which the government should regulate food fortification. A typical label for a fortified food is shown by Label No. 6.

1. What should be the criteria for fortifying a food? Is the nature of a food or its place in the diet important? Is the occurrence of a real or suspected nutrient deficiency disease in any part of the U.S. population the only signal that some food should be fortified?

2. Are there types of foods that should not be fortified with nutrients?

3. Should the government regulate food fortification to prevent unnecessary fortification even if the fortification is safe? If fortification is unnecessary, should the food be prohibited? Explain your answers.

4. Should the extent of fortification be based on a standard such as the U.S. Recommeded Dietary Allowance?

5. If the government were to regulate fortification, should prior approval be required before a food can be fortified, or should a manufacturer be able to fortify with the government later bringing a court challenge when it believes the fortification to be illegal?

6. Is the standard of identity the kind of regulation that the government should use to continue regulating food fortification? (It is the tradi-

tional way for such foods as enriched bread and skim milk fortified with vitamins A and D, and a few others.) If not, what other kind of regulation should be used? Should changes in the nutrient profiles of current food standards be made (either by eliminating nutrients or adding nutrients or changing levels)?

7. Do you have other suggestions on food fortification and labeling?

Total Food Label

Labels have a limited amount of space on which there is a large quantity of information. Some information is required by law: common or usual name of the food; name and address of packager, manufacturer or distributor; listing of ingredients for most foods; presence of artificial flavoring, coloring or preservative; and the amount of food contained in the package. Nutrition labeling is required by regulation if vitamins, minerals or protein are added to the food or if nutrition claims are made. The nutrition label may contain up to 28 items of information, such as the amount of vitamins, minerals, calories, protein, carbohydrate and fat present. In addition, the label may contain other information that the manufacturer wishes to put on it, such as brand name, price, vignettes or product photographs, serving directions, a code number related to the date of manufacture, recipe suggestions, offer to send information, premium offers, product guarantee, product coupons, advertising/benefit claims, ethnic symbols, universal product code, patent numbers, storage directions and name and address of container manufacturer. An example is shown by Label No. 7, Canned Sweet Corn.

In view of the quantity and complexity of package information, some people feel that the total communication effectiveness of package labels should be evaluated. Furthermore, additional information increases manufacturers' costs, and these costs may be added to the price of the food. Some manufacturers say they have to spend money to obtain the information, and, in some instances, have to adopt a fixed source of supply for some ingredients rather than use the lowest cost ingredients available at a particular time because varying the ingredients would require a change in the label. We need to determine what information should be conveyed by labels and how that information can be most effectively presented.

A number of proposals have been made to require additional information on labels including:

More specific identification of ingredients.
Amounts of ingredients.
Drained or fill weight.
Open date labeling.
Nutrition information.

In addition, proposals have been made to use symbolic markings or graphics to display information on nutrient content and certain food and color additives. Specific questions about ingredient, open date and nutrition labeling were discussed in other sections. Comments are invited on the following general questions concerning additional information needs and the total food label.

1. What type of product information should be conveyed using labels? How will this information benefit you?

2. Some people are concerned about "information overload," that is, having so much information on the label that it's confusing, overwhelming, or just hard to find what you want. Do you think that information overload is a problem with current labels? Would it be a problem if labels were required to have additional information?

3. Food packages are sometimes too small to accommodate a large amount of information on the label. Because of this, it may be necessary to limit label information. What current or proposed information on labels is most important? Least important? Put your answers to question No. 1 in order of priority. Does the importance of various types of label information change depending on the type of food products?

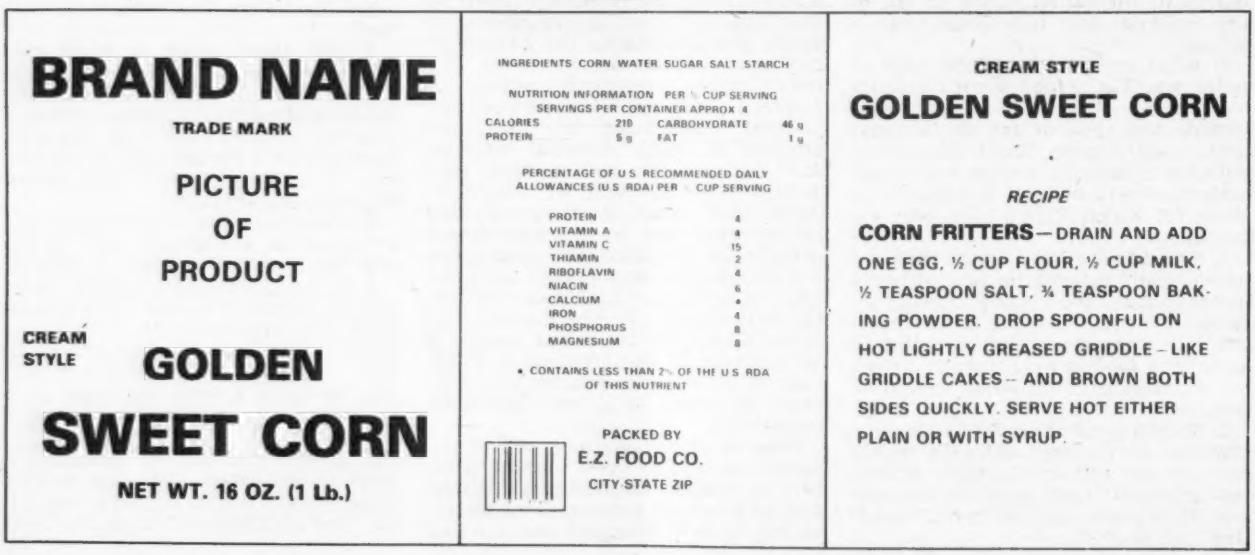
4. Do you have suggestions for improving the format or arrangement of food labels? Are there certain types of information that should be required to appear at different locations on the label?

5. Consumer representatives have suggested that symbolic markings on labels be used to call attention to the presence of a particular ingredient, such as an artificial flavor or color. This system might help people avoid certain ingredients to which they are abnormally sensitive. Do you favor this proposal? If so, give examples of specific ingredients that should be identified by symbols. How would people learn about what symbols mean?

6. Product labels are not the only method of conveying information to consumers. Other means that could be used in addition to labels include placards on display at point of sale, booklets for use in stores or at home, package inserts, etc. What role, if any, do you propose for other media?

7. What other suggestions do you have about the total food label? Give examples of labels that you think are understandable and complete. Which labels do you like best? Why?

Label 7


BRAND NAME
TRADE MARK
PICTURE
OF
PRODUCT
CREAM STYLE
GOLDEN
SWEET CORN
NET WT. 16 OZ. (1 Lb.)
INGREDIENTS CORN WATER SUGAR SALT STARCH
NUTRITION INFORMATION PER ½ CUP SERVING
SERVINGS PER CONTAINER APPROX 4
CALORIES 210 CARBOHYDRATE 46 g
PROTEIN 5 g FAT 1 g
PERCENTAGE OF U S RECOMMENDED DAILY ALLOWANCES (U S RDA) PER ½ CUP SERVING
PROTEIN 4
VITAMIN A 4
VITAMIN C 15
THIAMIN 2
RIBOFLAVIN 4
NIACIN 6
CALCIUM *
IRON 4
PHOSPHORUS 8
MAGNESIUM 8
* CONTAINS LESS THAN 2% OF THE U S RDA OF THIS NUTRIENT
PACKED BY
E.Z. FOOD CO.
CITY STATE ZIP
CREAM STYLE
GOLDEN SWEET CORN
RECIPE
CORN FRITTERS—DRAIN AND ADD ONE EGG, ½ CUP FLOUR, ½ CUP MILK, ½ TEASPOON SALT, ¾ TEASPOON BAKING POWDER. DROP SPOONFUL ON HOT LIGHTLY GREASED GRIDDLE – LIKE GRIDDLE CAKES – AND BROWN BOTH SIDES QUICKLY. SERVE HOT EITHER PLAIN OR WITH SYRUP.

SAFE AND SUITABLE INGREDIENTS

FDA has issued regulations, called standards of identity, that describe the kinds of ingredients that can or must be used in making many traditional foods. Under the law, FDA can issue a food standard when the standard "will promote honesty and fair dealing in the interest of consumers." Standards of identity have been issued for milk, cheeses, frozen desserts, bread, flour, macaroni, canned fruits, canned vegetables, and other foods. Foods for which no standards of identity have been issued, such as soups, cookies and pizza, are called nonstandardized foods. In nonstandardized foods manufacturers may use any ingredients desired, but must give the food an honest and nonmisleading name, and declare all ingredients in the ingredient statement.

In the past, standards of identity were like recipes, naming the specific ingredients that could be used. These standards often allowed several optional ingredients to be used. For example, canned peas may be seasoned with one or more of the following optional seasonings: green or red peppers, mint leaves, onions, garlic, horseradish, lemon juice, butter or margarine. Thus, even under the recipe-type standard, manufacturers often have had some flexibility in making the food, and the food could vary to some degree in taste and other features.

In recent years, manufacturers have been allowed additonal flexibility in choosing optional ingredients in standardized foods. Instead of listing by name in a recipe the specific ingredients that could be used, some standards pemit any safe and suitable ingredient to be used for certain purposes. For example, instead of specifying the particular preservatives that could be used by name (calcium propionate, sodium benzoate, etc.), a standard might allow any "safe and suitable preservative" to be used.

When safe and suitable ingredients are permitted to be used in a particular standard, FDA believes that the additional flexibility would not change the basic character of the food. The "safe and suitable" approach also allows a manufacturer or food processor to use different ingredients because of seasonal changes or to take advantage of new ingredients and economic conditions. Previously, such flexibility could be achieved by seeking to amend the applicable regulations. Amendment is a lengthy and elaborate procedure, even where the changes do not affect the character or nutritional value of the finished food.

Only safe ingredients can be used in any food, including a standardized food.

An ingredient is considered suitable only if it performs an appropriate function in the food in which it is used. The government would not consider an ingredient to be suitable if its use significantly changed or degraded the basic characteristcs of the food. Characteristics in this sense include nutritional value, taste, smell, appearance, stability, etc.

Standards vary in how much flexibility they provide in using safe and suitable ingredients. Some examples: the authorization to use safe and suitable preservatives in the cane syrup standard; safe and suitable nutritive sweeteners in a number of food standards, including the sweetened condensed milk standard; safe and suitable breading ingredients in the frozen raw breaded shrimp standard; any safe and suitable optional ingredient, except vitamins and certain other ingredients, in the soda water standard; and safe and suitable milk-derived ingredients to build solids in the creaming mixture for cottage cheese.

FDA revised the ice cream standard to permit any safe and suitable milk-derived ingredient to be used to meet the minimum dairy requirements. FDA received objections to this change because some people thought the change would lower the nutritional quality of the food or alter its character. FDA revoked this change because of a possible difference in nutritional quality, and it is no longer in effect.

1. Do you think food standards are a good way to regulate foods? What alternatives would you suggest? For which foods are standards of identity needed? Why?

2. Do you think standards of identity should provide flexibility in the use of optional ingredients? Do you agree that a food processor or manufacturer should have the ability to use new ingredients in a standardized food? If the change does not significantly alter what the food is? If the food is informatively labeled?

3. Does the "safe and suitable" policy allow too much flexibility in the way standardized foods are made? Which of the examples of the use of "safe and suitable" ingredients given above do you agree or disagree with and why? If you disagree with any of the uses, would you have a different view if more information about the ingredients were provided on the labels?

4. Do you think there would be as much need for standards of identity if the labels for all foods provided more information, such as information in the name about the percentage of important ingredients, percentage ingredient labeling, nutrition information, or other information? Which do you think is more important, to have more standards of identity, or to have more information on the labels of all foods? If more information is desirable, specify what information.

5. What factors should be considered in determining whether the use of a new option ingredient alters the basic character of a food? Do you think that the use of new ingredients that are similar to existing ingredients alters the basic character of a food? Does

your answer depend on the type of food involved?

6. Should food standards always specify the specific function (preservative, flavor, sweetener, etc.) for which safe and suitable ingredients may be used? For example, the soda water standard permits the use of any safe and suitable optional ingredients without specifying the functions for which the ingredients may be used? Should this be changed? How?

7. Do you have any other suggestions about food standards or about the use of safe and suitable ingredients?

REFERENCES

FEDERAL FOOD, DRUG, AND COSMETIC ACT REGULATIONS—TITLE 21 CODE OF FEDERAL REGULATIONS

Sec.
101.3(e) Imitation labeling; nutritional inferiority.
101.4 Designation of ingredients; order of predominance; specific versus collective names.
101.6 Label designation of ingredients for standardized foods.
101.9 Nutrition labeling of food.
101.22 Labeling of spices, flavorings, colorings and chemical preservatives.
101.25 Labeling of foods in relation to fat and fatty acid and cholesterol.
102.5 Common or usual name for non-standardized foods; characterizing ingredient.
102.54 Name of seafood cocktail.
105 Labeling of foods for special dietary use.
130.3 General provisions for food standards; safe and suitable.
131-169 Specific food standards.

Examples

135 Frozen desserts.
136 Bakery products.
145 Canned fruits.
165 Nonalcoholic beverages.
166 Margarine.
169 Food dressings and flavorings.
131-169 Safe and suitable.

Examples

131.120 Sweetened condensed milk.
133.128 Cottage cheese.
161.175 Frozen raw breaded shrimp.
165.175 Soda water.
168.130 Cane syrup.

STATUTORY PROVISIONS

Federal Food, Drug, and Cosmetic Act citations are listed in the first column. The United States Code citation is given in the second column.

Sec.	U.S.C.	
401	21 U.S.C. 341	Food standards.
403(a)	21 U.S.C. 343(a)	False and misleading claims.
403(c)	21 U.S.C. 343(c)	Imitation.
403(i)	21 U.S.C. 343(i)	Common or usual names; ingredient labeling; spices, flavorings and colorings.
403(j)	21 U.S.C. 343(j)	Special dietary foods.
403(k)	21 U.S.C. 343(k)	Labeling of artificial flavoring, artificial coloring or chemical preservatives; exceptions.
701(a)	21 U.S.C. 371(a)	Rulemaking authority.
701(e)	21 U.S.C. 371(e)	Procedures for food standards and certain other rules.

JUDICIAL DECISIONS

62 Cases of Jam v. *United States*, 340 U.S. 593 (1951)—Imitation labeling.

Federation of Homemakers v. *Schmidt*, 539 F. 2d 740 (D.C. Cir. 1976)—FDA regulation on imitation labeling.

[FR Doc. 78-15965 Filed 6-8-78; 8:45 am]